Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1-16. (Canceled)

17. (Currently Amended) A system comprising:

only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a <u>pre-formed predetermined</u> bulge region that protrudes configured to protrude radially outward from the body region when expanded, the <u>pre-formed predetermined</u> bulge region is positioned at a location between a proximal end and a distal end of the body region and at a predetermined location around a circumference of the body region-that extends less than the entire circumference of the body region, wherein the <u>pre-formed predetermined</u> bulge region is configured to have different pressure and/or inflation characteristics than the elongate body region; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, each of the moveable members being moveable independent of the other moveable members, the stent body being expandable from an unexpanded condition to an expanded condition by expansion of the single balloon extending within the stent wall from at least a proximal end to at least a distal end of the stent body, in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and aligned with the <u>pre-formed predetermined</u> bulge region of the single balloon, and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall by the expansion of the predetermined bulge region of the single balloon to form a scaffold, the scaffold defining a side opening in the stent wall;

wherein the pre-formed bulge region is configured to protrude radially outward from the body region independently of whether or not the bifurcated stent is disposed on the single balloon.

18. (Canceled)

19. (Previously Presented) The system of claim 17 wherein the plurality of movable members are characterized as being self-expandable, balloon expandable or hybrid expandable.

20-38. (Canceled)

- 39. (Previously Presented) The system of claim 17 wherein at least a portion of the bifurcation stent is constructed from a shape-memory material.
- 40. (Previously Presented) The system of claim 17 wherein at least a portion of the bifurcation stent is constructed from a metal selected from the group consisting of stainless steel, nitinol, Elgiloy, shape-memory material, and any combination thereof.

41. (Canceled)

- 42. (Previously Presented) The system of claim 17 wherein when the balloon is expanded the bulge region of the balloon extends the plurality of movable members radially outward from the stent wall to form the scaffold.
- 43. (Previously Presented) The system of claim 17 wherein the body region of the balloon has a thickness, the thickness of the body region being greater than the thickness of the bulge region.
- 44. (Previously Presented) The system of claim 17 wherein the body region of the balloon has a thickness, the thickness of the body region being less than the thickness of the bulge region.

- 45. (Previously Presented) The system of claim 17, wherein the bulge region is positioned on an exterior surface of the body region between the proximal and distal ends of the body region.
- 46. (Previously Presented) The system of claim 17, wherein the movable members include a shape memory material, and expansion of the single balloon within the stent body activates the shape memory material to move the movable members into the radially outward extended position.

47. (Currently Amended) A catheter system comprising:

a catheter having a balloon arrangement, the balloon arrangement including an elongate body portion and a <u>pre-formed</u> bulge portion configured to protrude radially outward from the body portion when expanded, the bulge portion being positioned at a location between a proximal end and a distal end of the body region and positioned at a predetermined circumferential location around a circumference of the body region, the bulge portion extending around less than an entire circumference of the body region, wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, at least one of the moveable members being separate from the other moveable members, the stent wall being expandable from an unexpanded condition to an expanded condition by expansion of the body portion of the balloon arrangement, and the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement to define a side opening in the stent, wherein the bulge portion is positioned within the circumferential plane prior to expansion of the bulge portion, and after expansion of the bulge portion a portion of the bulge portion extends radially through the side opening outside the circumferential plane.

- 48. (Previously Presented) The system of claim 47 wherein when the body portion and the bulge portion expand simultaneously.
- 49. (Previously Presented) The system of claim 47 wherein the body portion of the balloon has a thickness, the thickness of the body portion being greater than a thickness of the bulge portion.
- 50. (Previously Presented) The system of claim 47 wherein the body portion of the balloon has a thickness, the thickness of the body portion being less than a thickness of the bulge portion.
- 51. (Previously Presented) The system of claim 47 wherein when the body portion and the bulge portion are integrally formed as a single piece.
- 52. (Previously Presented) The system of claim 47 wherein the bulge portion has a generally hemispherical structure when expanded.
- 53. (Previously Presented) The system of claim 47, wherein the bulge portion is positioned on an exterior surface of the body portion between proximal and distal ends of the body portion.
- 54. (Previously Presented) The system of claim 47, wherein the body portion of the balloon extends coaxially with the stent body.
- 55. (Previously Presented) The system of claim 47, wherein the body portion of the balloon has a distal end that extends distally of a distal end of the stent body, and a proximal end that extends proximally of a proximal end of the stent body.
- 56. (Previously Presented) The system of claim 47, wherein the bulge portion extends from within the stent body to a position outside the stent body when expanded.

- 57. (Currently Amended) A catheter system comprising:
- a catheter having a balloon arrangement, the balloon arrangement including an elongate body portion; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, the movable members configured as self expandable structures that move from an unexpanded position retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall, wherein expansion of the stent wall causes the movable members to move from the unexpanded position to the expanded position, at least a portion of the moveable members expanding towards a proximal end of the stent body and at least a portion of the moveable members expanding towards a distal end of the stent body;

wherein the balloon arrangement further includes a <u>pre-formed predetermined</u> bulge portion configured to extend radially outward from the elongate body portion when inflated, the <u>pre-formed predetermined</u> bulge portion being positioned at a location between a proximal end and a distal end of the body region and extending around less than an entire circumference of the body portion, the stent positioned relative to the elongate balloon to position the movable members in axial and radial alignment with the <u>pre-formed predetermined</u> bulge portion.

- 58. (Previously Presented) The catheter system of claim 57, wherein the movable members include a shape memory material.
 - 59. (Canceled)
- 60. (Previously Presented) The catheter system of claim 57, wherein inflation of the bulge portion aids the movable members to move from the unexpanded position to the expanded position.
 - 61. (Currently Amended) A catheter system, comprising:

only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a <u>pre-formed predefined</u> bulge

region configured to protrude radially outward from the body region when expanded, the <u>preformed predefined</u> bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the <u>pre-formed predefined</u> bulge region extending less than the entire circumference of the body region; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall and movable between an unexpanded position within the circumferential plane and an expanded position extending radially outward from the circumferential plane to define an aperture in the circumferential wall, the single balloon extending within the stent body from at least a distal end to at least a proximal end of the stent wall, the stent wall being expandable by expansion of the body region of the single balloon and the movable members being expandable by expansion of the pre-formed predefined bulge region of the single balloon, wherein a first moveable member extends radially outward at a location distal of the aperture in the circumferential wall and a second moveable member extends radially outward at a location proximal of the aperture.

62. (Canceled)

63. (Currently Amended) A catheter system for treating a bifurcated vessel, the catheter system comprising:

a stent including a substantially tubular stent body having an open proximal end and open distal end, wherein a portion of the stent body intermediate the open proximal end and open distal end includes a plurality of movable members configured to move between an unexpanded position and an expanded position, wherein when in the expanded condition, the plurality of moveable member extend radially outward from stent body to define an aperture; and

an inflatable balloon, the inflatable balloon including an elongate body region having a <u>pre-formed</u> bulge region configured to protrude radially outward from the body region when inflated, wherein the bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the bulge region extending less than the entire circumference

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of the body region, wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region;

wherein the stent is disposed about the balloon such that the bulge region of the balloon is aligned with the plurality of movable members of the stent, wherein the elongate body region of the balloon is configured to expand the tubular stent body when inflated, and the bulge region of the balloon is configured to move the plurality of movable member from the unexpanded position to the expanded position when inflated.